UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,454	02/08/2005	Monique Berwaer	2004_0980A	2307

513 7590 04/19/2007

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/500,454	BERWAER ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,6 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,6,8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Submission filed 2/23/2007, including amendment, remarks, and declaration, has been received. Pursuant to amendment, claims 3, 4, 6, and 8 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, and 7 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,464,376 to Sunshine et al. in view of US 5,869,479 to Kreutner et al. for reasons of record and those discussed below. In addition, **new claim 8** is now included in this rejection.

With regard to the amendment to claim 3, this amendment in part incorporates the limitations previously in claim 5, which is now cancelled. Claim 5 was previously rejected as unpatentable over this art, thus adding the limitation formerly in claim 5 to independent claim 3 does not overcome the art. With regard to the new limitation specifying the ratio of immediate release to controlled release active agent, this is a matter of dosing, which is recognized in the art to be an optimizable parameter. In general, optimization of a parameter that is recognized as being optimizable, without more, does not provide a basis for patentability. With regard to new claim 8, this claim merely recites the optimal dosage of the active agent. It is generally obvious to use the optimal dosage of an active pharmaceutical ingredient in order to treat the condition of

interest. A person of ordinary skill in the art has a reasonable expectation of success of determining this optimal dosage.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' rely on declaration to show that the instant invention does not significantly alter the bioavailability or maximum plasma concentration of the active agent when ingestion occurs before or after a meal. This is not persuasive for several reasons. First, the declaration is deficient in that it does not compare the invention to the closest prior art. In this case the closest prior art would be the art-known immediate release formulation. The declaration, which compares the claimed invention to some other formulation that is not the formulation of the art, is not helpful in showing differences between the claimed invention and the closest prior art. Second, the limitation "before a meal or after a meal" is so broad as to be effectively meaningless. With the exception of a newborn who ingests the medicament of interest before consuming nourishment and who subsequently dies without ever eating, **any** ingestion of a medicament is "before a meal or after a meal", since the claim does specify how long before or after a meal the supposedly unexpected result is in force.

Applicants also argue that efletirizine cannot be compared to similar medicaments such as loratadine when formulated for daily-dose tablets, because the two have very different pharmokinetics. This is not persuasive for several reasons. First, the claims are not limited to daily-dose tablets, so it is not clear that the argument is applicable to the claims at issue. The claims are to a composition, which may or may

not be a daily-dose tablet; the intended use of a composition is not generally afforded patentable weight. Furthermore, Applicant admits that the problem of efletirizine compositions not rapidly reaching an effective plasma concentration is known in the art (see response, page 6). The art clearly recognizes the benefit of anti-inflammatory agents rapidly reaching effective concentrations in the subject; Sunshine teaches an anti-inflammatory in a prolonged-release formulation that also includes an immediate release component.

With respect to the question of the artisan enjoying a reasonable expectation of success, Applicants' have argued that such would be lacking because the working examples of Kreutner only use long-half life agents, and thus they do not teach the artisan how to use eflitirazine, which is a short-half life agent. This argument is not persuasive, because Kreutner's claims encompass a prolonged release formulation of eflitirazine. Since Kreutner is a valid issued US Patent, its claims are understood to comply with all applicable statutes, including the enablement requirement of 35 USC 112, first paragraph. As such, it cannot be said that Kreutner does not teach the artisan how to make long-acting pharmaceuticals with eflitirazine.

Ultimately, a rejection under 35 USC 103(a) boils down to the question of whether or not it would have been obvious to a person of ordinary skill in the art to, at the time of the invention, do what Applicant has done, and would the artisan enjoy a reasonable expectation of success at doing so. The problem that is solved by the composition of instant claims is how to make a prolonged release composition that offers a benefit to the user quickly, instead of taking a long time to be effective. The

solution to this problem, as defined by the claims, is to make a combination immediate-release and prolonged-release formulation. The prior art (Sunshine) already offers the same solution to the same problem. Sunshine makes an anti-inflammatory composition that quickly reaches effective concentration and has a prolonged release profile by using a combination of a sustained-release formulation and an immediate-release formulation in the same dosage form. While Sunshine does not use eflitirazine, the art recognizes eflitirazine as an anti-inflammatory (Kreutner), which is used to treat the same type of disorders (inflammations). Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to do what Applicant has done, namely, to make a composition of eflitirazine that contains both a controlled-release component and an immediate-release component. To the extent that Applicants' are correct in arguing that one cannot simply replace the drugs of Sunshine with eflitirazine, the only manipulation required is that of optimizing the dosage and release rate (in the extended release portion), for which the artisan can expect a reasonable expectation of success.

Claim 6 **remains** rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,464,376 to Sunshine et al. in view of US 5,869,479 to Kreutner et al. and Guy et al. (US 3,906,086) for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' argue that Guy does not remedy the deficiencies in Sunshine and Kreutner. These alleged deficiencies have been addressed, *supra*.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 6, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites, in part, "does not significantly alter either the bioavailability or maximum plasma concentration". However, it is not clear from the specification, nor is it recognized in the art, how much of such alterations are significant. As such, the artisan would be unable to determine the metes and bounds of the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD
Art Unit 1615

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600